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Request For Continued Examination (RCE) Transmittal

Address to:
Commissioner for Patents
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Washington, DC 20231

Application Number	09/580,797
Filing Date	May 30, 2000
First Named Inventor	Peter C. Iwen
Art Unit	1634
Examiner Name	Goldberg, Jeanne Anne
Attorney Docket Number	UNMC63149

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

1. Submission required under 37 CFR 1.114

- a. ☐ Previously submitted
- i. ☐ Consider the amendment(s)/reply under 37 CFR 1.116 previously filed on _____
(Any unentered amendment(s) referred to above will be entered).
- ii. ☐ Consider the arguments in the Appeal Brief or Rely Brief previously filed on _____
- iii. ☐ Other _____
- b. ☒ Enclosed
- i. ☒ Amendment/Reply
- ii. ☒ Affidavit(s)/ Declaration(s)
- iii. ☐ Information Disclosure Statement (IDS)
- iv. ☐ Other _____

2. Miscellaneous

- a. ☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of _____ months. (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)
- b. ☐ Other _____

3. Fees

- The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.
The Director is hereby authorized to charge the following fees, or credit any overpayments, to
- a. ☒ Deposit Account No. 04-1406
- i. ☒ RCE fee required under 37 CFR 1.17(e)
- ii. ☒ Extension of time fee (37 CFR 1.136 and 1.17)
- iii. ☐ Other _____
- b. ☒ Check in the amount of \$ 1100.00 _____ enclosed
- c. ☐ Payment by credit card (Form PTO-2038 enclosed)

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

Name (Print/Type)	Tong Li	Registration No. (Attorney/Agent)	47,748
Signature		Date	7/24/03

CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner For Patents, Box RCE, Washington, DC 20231, or facsimile transmitted to the U.S. Patent and Trademark Office on the date shown below.

Name (Print/Type)	Jane C. Bogan	Date	July 24, 2003
Signature			

Page 1 of 2

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Box RCE, Washington, DC 20231.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of) Group Art Unit: 1634
)
Peter Iwen et al.) Examiner: J. Goldberg
)
Serial No. 09/580,797)
)
Filed: May 30, 2000)
)
For: "MATERIALS AND METHODS)
FOR MOLECULAR DETECTION)
OF CLINICALLY RELEVANT,)
PATHOGENIC FUNGAL SPECIES")

REQUEST FOR CONTINUED EXAMINATION**UNDER 37 C.F.R. §1.114**

The Final Official Action and the Advisory Action and the references cited therein have been carefully reviewed. The present remarks, which are responsive to both of the foregoing Official Actions dated July 25, 2002 and March 11, 2003, respectively, in the above-identified patent application, are being filed as part of the submission required under 37 C.F.R. §1.114, in connection with the Request for Continued Examination, which is submitted concurrently herewith.

Also provided herewith is a second Declaration of Dr. Iwen under C.F.R. §1.132 demonstrating the superiority of the presently claimed primer set over the prior art primer sets of White et al.

**CLAIMS 2-5, 20, AND 21 ARE NOT RENDERED OBVIOUS BY THE PRIOR ART
CITED BY THE EXAMINER**

Applicants again reiterate all of the currently rejected claims, claims 2-5, 20, and 21, require a primer set consisting of SEQ ID NO: 1 and SEQ ID NO: 2, which is capable of amplifying *Aspergillus ustus* (SEQ ID NO: 3), *Aspergillus terreus* (SEQ ID NO: 4), *Aspergillus niger* (SEQ ID NO: 5), *Aspergillus fumigatus* (SEQ ID NO: 6), *Aspergillus flavus* (SEQ ID NO: 7), and

Aspergillus nidulans (SEQ ID NO: 8). As the Examiner acknowledges none of the references, alone or combination, teach detection of specific *Aspergillus* species by amplifying a fragment using the instantly claimed primer set consisting of SEQ ID NO: 1 and SEQ ID NO: 2. Further, as evidenced by the Declaration of Dr. Iwen submitted herewith, none of the references cited by the Examiner teach, or render the instantly claimed primer set obvious, nor are the prior art primer sets "functionally equivalent" to those presently claimed.

Specifically, in the previously submitted Declaration of Dr. Peter Iwen comparative evidence is provided which demonstrates that in contrast to the primer set instantly claimed, the primer set of White et al., namely ITS1/ITS4, is not capable of amplifying *A. terreus*, only weakly amplifies *A. flavus* and *A. nidulans* and thus is not **functionally equivalent** to the primer set of the present invention, i.e., SEQ ID NO: 1/SEQ ID NO: 2.


However, in the Advisory Action, the Examiner contends that the previously submitted declaration does not compare the claimed primer set, SEQ ID NO: 1/SEQ ID NO: 2 to the closest prior art, namely ITS5/ITS4 of White et al. Accordingly, it is the Examiner's position that the Declaration and the evidence presented therein are insufficient to overcome the art rejections of record.

In response, Applicants hereby submit this Request for Continued Examination and a second Declaration of Dr. Iwen, attached hereto. This Declaration provides further comparative evidence demonstrating that the primer set of White et al., namely ITS5/ITS4, is not functionally equivalent to the primer set of the instant invention. Particularly, a comparison of Figures 1 and 2 show that the sensitivity of the instantly claimed primer set is much greater than that of the ITS5/ITS4 primer set of White et al. As shown in Figure 2, the White et al. primer set is incapable of amplifying *A. fumigatus* and *A. terreus* on DNA samples diluted 1:100 in contrast to the instantly claimed primer set. Inasmuch as the present method is

to be performed on patient this reduced sensitivity could result in a misdiagnosis or a failure to identify an Aspergillus infection in patient samples.

In summary, none of the cited references, alone or in combination teach the instantly claimed primer set, SEQ ID NO: 1/SEQ ID NO: 2. Moreover, as evidenced by the Declarations of Dr. Iwen, not all primers within the 28S region are functionally equivalent or exhibit comparable sensitivity. Accordingly, none of the cited references renders the instantly claimed primer set obvious. Thus, the rejection of Claims 2-5, 20, and 21 under U.S.C. §103(a) as allegedly unpatentable over White et al. and others is improper and should be withdrawn.

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Enclosures: Declaration of Dr. Peter Iwen
Exhibit A
Curriculum Vitae of Dr. Peter Iwen